Complete Summary

GUIDELINE TITLE

Diagnosis and management of vulvar skin disorders.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Diagnosis and management of vulvar skin disorders. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2008 May. 11 p. (ACOG practice bulletin; no. 93). [90 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

 $\label{eq:METHODOLOGY-including Rating Scheme and Cost Analysis} \\$

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Vulvar skin disorders, including:

- Vulvar dermatoses: contact dermatitis, lichen simplex chronicus, lichen sclerosus, lichen planus
- Vulvar atrophy
- Genital human papillomavirus (HPV) infection
- Paget disease
- Crohn's disease

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Infectious Diseases Obstetrics and Gynecology Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review diagnostic approaches and provide a structured framework for the management of vulvar disorders

TARGET POPULATION

Women and female children and adolescents with symptoms of vulvar disorders

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation and Diagnosis

- 1. Evaluation of signs and symptoms (e.g., vulvar pain, pruritus)
- 2. Medical history
- 3. Search for common vulvar irritants and allergens
- 4. Vulvar biopsy
- 5. Additional diagnostic tests (e.g., culture, microscopy, vaginal pH)

Treatment and Management

- 1. Topical therapies
 - Estrogen and testosterone creams
 - Topical steroid cream (clobetasol propionate)
 - Nonhormonal vaginal moisturizer
- 2. Systemic immunosuppressive therapies
- 3. Surgery
- 4. Further evaluation of biopsy-confirmed Paget disease

MAJOR OUTCOMES CONSIDERED

- Symptom relief
- Sexual function

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and August 2007. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- $\mbox{\bf Level C}-\mbox{\bf Recommendations}$ are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendation is based on limited or inconsistent scientific evidence (Level B):

• The recommended treatment for lichen sclerosus is an ultrapotent topical corticosteroid, such as clobetasol propionate.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Biopsy of hyperpigmented or exophytic lesions, lesions with changes in vascular patterns, or unresolving lesions is particularly important and should be performed to rule out carcinoma.
- For patients with biopsy-confirmed Paget disease, further evaluation of the breast, genitourinary tract, and gastrointestinal tract should be undertaken.

Definitions:

Grades of Evidence

- **I** Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendation

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and appropriate management of vulvar skin disorders

POTENTIAL HARMS

- Side effects of:
 - Topical estrogen therapy in girls
 - Topical steroid therapy
 - Systemic immunosuppressants
- When compared in randomized controlled trials with either estrogen tablets or with the estrogen ring, conjugated equine estrogen cream was found to be significantly associated with adverse effects, including bleeding, breast pain, and perineal pain.
- All forms of topical estrogen therapy increase the possibility of endometrial hyperplasia and overstimulation.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 May

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins - Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 29, 2008. The information was verified by the guideline developer on August 20, 2008.

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